Severe Acute Respiratory Syndrome (SARS): Public Health Situation and U.S. Response

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SUMMARY

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Severe Acute Respiratory Syndrome (SARS): Public Health Situation and U.S. Response

Severe Acute Respiratory Syndrome (SARS) is a new influenza-like disease; the overall case fatality rate is currently estimated to be about 15%. Scientists have isolated a previously unknown type of coronavirus which they believe is the cause of the disease. The genetic material of the SARS virus has been sequenced and this may be helpful in determining the origin of the virus and understanding its behavior as well as developing a treatment and a vaccine. Currently, all tests for SARS infection are considered experimental. The World Health Organization (WHO) and others are working to develop a reliable diagnostic test which can be used to confirm a clinical diagnosis of SARS.

Federal, state and local public health agencies share responsibility for a range of different activities that are important in effectively reacting to and ultimately overcoming a disease outbreak such as SARS. In investigating the SARS outbreak, the most important activities are case detection, patient isolation and contact tracing using disease surveillance systems as well as epidemiology and laboratory services. Other important public health measures include the development and coordination of emergency medical response plans, the regulation of environmental conditions that impact health, and the rapid and clear communication of information between all levels of the public health agencies, healthcare personnel, the media and the public.

The states have primary responsibility for protecting the health and welfare of their citizens. The federal government, through the Secretary of Health and Human Services (HHS), is responsible for preventing the introduction and spread of communicable diseases from foreign countries into the United States at international ports or from one state into another. HHS is also responsible for overall health policy making and public health protection. Among the federal agencies within HHS, those primarily involved in the U.S. response to the SARS outbreak are the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA).

The U.S. public health system has received dramatic funding increases over the past 2 years to strengthen the public health infrastructure and enhance its capacity to respond to emergencies such as a bioterrorist attack or outbreak of infectious disease. Consequently, many analysts will be evaluating the U.S. reaction to the SARS epidemic to identify any gaps in the public health system response and address them accordingly, in order to be better prepared for any future event involving bioterrorism or emerging infectious disease.

Contents

Severe Acute Respiratory Syndrome (SARS): Public Health Situation and U.S. Response

Medical Background

Severe Acute Respiratory Syndrome (SARS) is a new infectious disease that causes flu-like symptoms which may progress to pneumonia. The incubation period is 2-7 days but may be up to 10 days. Symptoms include fever, malaise, chills, headache, body ache, coughing, difficulty breathing, and diarrhea. The disease course and recovery period may take as long as 3 weeks. In 10% of SARS cases the symptoms are severe and patients need mechanical assistance to breathe. The more severe form of SARS tends to occur in people over 40 years of age. The World Health Organization (WHO) estimates the overall case fatality rate is about 15% and over 50% in persons 65 years or older.[1] Mortality is higher in people with underlying chronic disease (hepatitis B, diabetes, hypertension, heart disease, stroke) or in those who sought treatment at a late stage of SARS.

SARS was first recognized in Vietnam in late February 2003 by a WHO epidemiologist and on March 12, 2003, WHO issued a global alert on SARS. The new disease was later linked to an outbreak of respiratory disease that began in mid-November 2002 in Guangdong Province, China. As of May 22, 2003, a total of 8,046 SARS cases and 682 deaths have been reported to WHO from 28 countries on 5 continents.[2] China, Hong Kong and Taiwan account for 93% of all reported cases and 91% of reported deaths. In these areas, public health experts are concerned that the disease has been spreading within the local community (rather than just within hospitals or households), indicating the probability of continued SARS cases. In the United States as of May 21, 2003, the Centers for Disease Control and Prevention (CDC) has received reports from 40 states of 355 cases and no SARS-related deaths; of the total, 290 are suspect cases and 65 are probable cases.[3]

In late March 2003 an international team of scientists announced the isolation of a previously unknown type of coronavirus which they believe is the cause of the

[1] WHO is the United Nations specialized agency for health worldwide. WHO estimates that the case fatality rate is less than 1% for persons age 24 or younger, 6% in persons 25 to 44 years, and 15% in persons 45 to 64 years. WHO Update 49, May 7, 2003. [http://www.who.int/csr/sars/en/]

[2] Current WHO SARS statistics can be found at: [http://www.who.int/csr/sars/en/].

[3] Current CDC SARS statistics can be found at [http://www.cdc.gov/od/oc/media/sars.htm].

disease.[4] Experiments in monkeys conducted by Dutch and U.S. scientists seem to confirm that a coronavirus is the cause of SARS. However, scientists in Canada and China believe co-infection with another agent (chlamydia or metapneumovirus) may also be involved. Scientists believe co-infection, or some other factor like genetics or hygiene, may explain why certain patients, called "superspreaders," seem to be particularly infectious to those around them. Coronaviruses are known to cause serious respiratory and enteric disease in farm animals and pets; slight genetic changes in the coronavirus greatly alter its lethality and the disease symptoms in animals. In humans, coronaviruses are thought to cause about 30% of common colds.

Patients with SARS shed virus in droplets of respiratory secretions created while coughing or sneezing as well as in their stool and urine. Although most SARS cases have occurred in people such as family members or healthcare workers who have had direct close contact with an infected person, a cluster of over 300 cases occurred in residents of a Hong Kong apartment complex where contaminated sewage is thought to have spread the disease. Like other human respiratory viruses, the SARS virus can survive 48 hours at room temperature and for longer periods at colder temperatures. Scientists in Hong Kong report that the SARS virus can survive for 72 hours on environmental surfaces such as stainless steel and plastic. The SARS virus may be unique, however, in its ability to survive for up to 4 days in stool samples from patients with diarrhea. Although detergents are not effective at inactivating the SARS virus, standard disinfectants, such as bleach and alcohol, are effective.

The genetic material of the SARS virus is composed of RNA rather than DNA.[5] All RNA viruses are inherently subject to a high level of mutations. Consequently, the SARS virus may change rapidly and evade drug treatments or vaccines. On April 12, 2003, researchers in Vancouver, Canada, released genome sequence data for one SARS virus isolate. This was followed a few days later by sequence data from CDC; several other labs have also sequenced additional SARS virus isolates. The labs are currently analyzing variations among the genome sequence data. This information may be helpful in determining the origin of the virus as well as understanding its behavior. The genome data might also help researchers develop treatments, a vaccine and diagnostic tests.

Currently, all tests for SARS infection are considered experimental. WHO and others are working to develop a reliable diagnostic test which can be used to confirm a clinical diagnosis of SARS. Because identifying a case of SARS is a diagnosis of exclusion, until a reliable SARS laboratory test is available the accuracy of reported SARS case numbers will rely on other laboratory tests to rule out alternative disease agents combined with a clinical diagnosis of SARS. Given the non-specific

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[4] Coronaviruses were first isolated from chickens in 1937. The name derives from its crown-like appearance when viewed with the electron microscope. This family of viruses are known to infect cattle, pigs, rodents, cats, dogs, and birds. Coronaviruses are a serious disease problem for agriculture, especially chickens.

[5] DNA, or deoxyribonucleic acid differs from RNA, ribonucleic acid, in the type of sugar group contained in the molecule. While the hereditary material of all living things and many viruses is composed of DNA, some viruses have RNA as the hereditary material.

symptoms of SARS, a clinical diagnosis will not be as precise as a laboratory test and will not include the expected much larger number of mild SARS cases. All known respiratory viruses cause a range of disease symptoms from mild to severe. Scientists have found some individuals who are infected with the SARS virus yet have only minimal symptoms. It is unknown if a patient with mild SARS can spread the disease to others. An accurate diagnostic test will identify such mild cases to help prevent the spread of the disease as well as gain a more accurate statistical picture on the extent of the SARS outbreak. If the SARS case definition is expanded to include mild disease cases, then the total number of SARS cases will increase thereby lowering the case fatality rate, currently estimated at 15%.

Scientists must learn more about the SARS disease process before they can identify what test (antibody, viral culture, polymerase chain reaction — PCR) to use on which specimen (throat or nasal swab, blood, stool, urine) for each stage of disease. An antibody test may not become positive for more than 3 weeks after symptoms begin, and not all patients mount an antibody response. A viral culture may not be positive at an early stage of disease or in all patient tissues. The PCR test, which indicates snippets of viral genome are present, may remain positive long after disease symptoms have resolved because defective (noninfectious) virus may continue to be present in the patient.

The media have reported on a SARS treatment developed in Hong Kong that some credit with helping patients overcome the disease. The treatment consists of ribavirin, an antiviral agent, and steroids, which act on the patient's immune response. However, because laboratory tests of ribavirin against coronavirus found the drug to be ineffective, some researchers speculate that these patients would get better even without treatment.[6] The issue is unlikely to be resolved until clinical trials are performed comparing various treatment regimens. Differences among countries in SARS deaths and case fatality rates are most likely due to patient delay in seeking medical care but may also be due to a more virulent virus or differences in how SARS patients are treated. Differences in the number of SARS cases among countries, especially in health care personnel, may reflect gaps or delays in imposing necessary infection control measures in hospitals.

Because SARS is a new disease and not completely understood, public health officials are very concerned about spread of the SARS virus and the "atypical" pneumonia and influenza-like symptoms associated with the disease. However, because in most countries SARS has not readily spread in the local community, many experts conclude that the SARS virus is not as contagious as the influenza virus. In contrast, past influenza epidemics have spread rapidly and been much more deadly. A 1968 flu outbreak spread worldwide within 8 weeks and caused 700,000 deaths. The 1918 influenza epidemic is said to have killed 20 million people worldwide. Scientists believe a similar deadly influenza epidemic is bound to reoccur in the future. In the United States,"typical" pneumonia and influenza kills 60,000 to 70,000

[6] Dennis Normile, Battling SARS on the Front Lines, *Science*, v. 300, May 2, 2003, pp. 714-715.

people each year (1,200 each week) primarily the elderly.[7] The number of deaths due to influenza in the United States has tripled over the past 25 years; influenza now kills three times as many people as AIDS.

U.S. Response

Federal, state and local public health agencies share responsibility for a range of different activities that are important in effectively reacting to and ultimately overcoming a disease outbreak.[8] In investigating the SARS outbreak, the most important activities are case detection, patient isolation and contact tracing using disease surveillance systems as well as epidemiology and laboratory services. Other important public health measures include the development and coordination of emergency medical response plans, the regulation of environmental conditions that impact health, and the rapid and clear communication of information between all levels of the public health agencies, healthcare personnel, the media and the public.

State and Local Public Health Agencies and Hospitals. The states have primary responsibility for protecting the health and welfare of their citizens. In general, all states have public health statutes that provide the authority for state and local officials to perform various public health functions such as collecting data, conducting inspections and enforcement activities, and licensing businesses, health care delivery facilities, physicians and other providers. The initial response to an outbreak of a new disease such as SARS begins at the local level with state and local public heath officials and healthcare personnel. Examples of such responses include active or passive disease surveillance systems, initial epidemiologic investigation, health care delivery, isolation and quarantine management. However, many states have inadequate procedures in place for patient isolation and quarantining of persons who are not yet ill but may have been exposed to an infectious agent and therefore are potentially infectious.[9] In general, state laws currently in effect address only diseases that were the cause of past epidemics, not new diseases such as SARS. Many states are reevaluating their isolation and quarantine laws and regulation. The Model State Emergency Powers Act has been under development since 2000 by public health experts as a guide for states in developing new response plans.[10]

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[7] In 1999 there were 63,730 deaths caused by pneumonia and influenza (P + I) in the United States, averaging 1,226 deaths per week. Of the 1999 total, 57,282 P + I deaths occurred in persons over 65 years of age (weekly average 1,102 deaths) and therefore 6,448 deaths occurred in persons under 65 years of age (weekly average 124 deaths). In the 25-44 years age group there were 1,402 deaths in 1999 due to P + I (weekly average of 27 deaths). *Health, United States, 2002*, Table 32, p. 127 and Table 33, p. 132. [www.cdc.gov/nchs/hus.htm]

[8] For a more in depth discussion of the public health infrastructure in the United States, see CRS Report RL31719, *An Overview of the U.S. Public Health System in the Context of Bioterrorism*, by Holly Harvey.

[9] For further information, see CRS Report RL31333, *Federal and State Isolation and Quarantine Authority*, by Angie Welborn and the CDC website a: [www.cdc.gov/ncidod/sars/quarantine.htm].

[10] A current draft is available at [www.turningpointprogram.org].

Department of Health and Human Services. At the federal level, HHS has primary responsibility for overall health policy making and public health protection. Among the federal agencies within HHS, those primarily involved in the U.S. response to the SARS outbreak are the CDC, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA).

On April 9, 2003, HHS Secretary Thompson met with vaccine manufacturers GlaxoSmithKline, Wyeth, Merck, and Aventis Pasteur and asked that they test all previously developed coronavirus vaccines as a possible SARS vaccine. Because of the high economic impact for agriculture, a number of animal vaccines have been developed against coronaviruses. In an address before the annual meeting of the Pharmaceutical Research and Manufacturers of America (PhRMA), Secretary Thompson asked that the companies test all previously identified antiviral agents for activity against the SARS virus. On April 4, 2003, officials from CDC, FDA, NIH and the HHS National Vaccine Program Office participated in a teleconference hosted by the PhRMA with more than 70 representatives of the pharmaceutical industry to discuss potential SARS diagnostics, drug treatments and vaccines.

Although the states have the authority to safeguard the public health within each state's individual borders, the federal government, through the Secretary of HHS, has primary responsibility for preventing the introduction and spread of communicable diseases from foreign countries into the United States at international ports or from one state into another.[11] On April 4, 2003, President Bush signed Executive Order 13295 which added SARS to the list of diseases for which involuntary quarantine can be used to prevent the transmission of a communicable disease.[12] Other diseases on the list include cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever and viral hemorrhagic fevers, such as Ebola, Marburg, and Lassa fever. SARS is the first disease to be added to the list in 20 years; the last disease added was Ebola in 1983.

Centers for Disease Control and Prevention. The FY2003 supplemental appropriation (H.R.1559, P.L. 108-11) included $16 million for SARS prevention and control activities at CDC. The agency is working closely with WHO and other partners in a global effort to address the SARS outbreak. Under WHO coordination, CDC scientists are in daily communication with scientists around the world, sharing their research findings on a secure Internet site, and exchanging laboratory reagents and specimens from SARS patients. On March 14, 2003, CDC activated its Emergency Operations Center to provide round-the-clock coordination and response. CDC has committed more than 300 medical and support staff to work on the SARS response. CDC has deployed about 30 doctors, epidemiologists, and other specialists to assist with onsite investigations around the world. CDC experts have held numerous media briefings to provide information on SARS research and surveillance findings and prevention measures. The CDC website is updated daily with information for physicians on clinical guidelines and prevention measures as well as

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[11] For more information, see *Fact Sheet on Legal Authorities for Isolation/Quarantine* at the CDC website [www.cdc.gov/ncidod/sars/factsheetlegal.htm].

[12] For more information on Executive Order 13295, see: [www.cdc.gov/ncidod/sars/factsheetlegal.htm]. The text of the Executive Order is available at [www.cdc.gov/ncidod/sars/pdf/executiveorder040403.pdf].

information for the public on SARS. In contrast to the fall 2001 anthrax outbreak, one federal government source, CDC, has been seen as providing timely, clear, and consistent information on SARS to the media and the public.

CDC has provided ongoing assistance to state and local health departments in investigating possible cases of SARS in the United States. On March 15, 2003, the agency issued an interim guidance for state and local health departments on enhanced surveillance for SARS and infection control measures to prevent spread of the virus to close contacts of SARS patients in hospitals and homes. The agency has conducted numerous teleconferences with state public health officials to provide them with the latest information on the disease and discuss the implementation of SARS surveillance and infection control measures. The agency has also issued interim guidance for the management of exposures to SARS and for cleaning of airplanes that have transported a SARS patient. CDC has issued a number of travel advisories and alerts as well as guidelines for persons who must travel to SARS affected areas.[13] The agency has distributed health alert notice cards to airline passengers entering the United States from SARS affected areas, alerting them to monitor their health and contact a physician if they develop fever or respiratory symptoms.

National Institutes of Health. NIH is responding to the SARS outbreak in the areas of diagnostics, therapeutics, vaccine development, drug screening and clinical research primarily through the efforts of the National Institute of Allergy and Infectious Diseases (NIAID). NIAID has long been involved in conducting and supporting research on emerging infectious diseases such as SARS through intramural and extramural research and collaborations with international organizations. In Hong Kong, a NIAID supported influenza surveillance program has collaborated with WHO and CDC in investigating the SARS outbreak and developing a diagnostic test. NIAID has funded the Respiratory Pathogens Research Unit at Baylor College of Medicine which has developed methods to detect human coronavirus and assess the immune response to coronavirus infection.

NIAID is supporting research on a SARS vaccine through the NIAID Vaccine Research Center on the NIH campus as well as through other intramural and extramural grants. The initial approach will focus on an inactivated (killed) virus vaccine, but NIAID also plans to support research on novel approaches such as genetically engineered vaccines, DNA-based vaccines, and live-attenuated vaccines. In response to a request from CDC, NIAID has sent 40 FDA-approved antiviral drugs to the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) for evaluation of efficacy against the SARS virus. NIAID is developing new antiviral agents, and passive immunotherapy (monoclonal and polyclonal antibodies) will also be investigated as a possible treatment for SARS.

Food and Drug Administration. On April 17, 2003, the FDA issued a guidance document on assessing blood donor suitability and blood product safety

[13] See the CDC website at [http://www.cdc.gov/ncidod/sars/travel.htm].

with respect to the current outbreak of SARS.[14] FDA is recommending additional questioning of potential donors to determine if they may be at elevated risk for SARS due to recent travel or due to exposure to a person with SARS. Although current FDA regulations require that all blood donors be in good health at the time of donation, the new guidance will allow for the temporary deferral of blood donors who may have been exposed to SARS. FDA estimates that the new guidance will have a minimal impact on the quantity of the blood supply; based on current travel estimates, at most 0.4% of donors will be deferred. The guidance document was issued for immediate implementation in order to assure the safety of the blood supply until more is learned about this new viral disease. Although the guidance applies to whole blood and blood components intended for transfusion and injectable and non-injectable blood products, establishments using other human cells or tissues may consider implementing similar donor screening practices.

FDA is also working with CDC and NIH in the battle against SARS to accelerate the development of new diagnostic tools, safe and effective treatments, and a safe and effective SARS vaccine. The Center for Devices and Radiological Health (CDHR) is working with CDC and private industry to bring a reliable SARS diagnostic kit to market as quickly as possible. The Center for Drug Evaluation and Research (CDER) is helping identify drugs that are active against the SARS virus and develop protocols to test these drugs in SARS patients. The Center for Biologics Evaluation and Research is working with other government agencies and the private sector to address early issues in the development of a SARS vaccine such as the use of animal test data, safe manufacturing practices, and clinical trial design.

Issues for Congress

The U.S. public health system has received dramatic funding increases over the past 2 years to strengthen the public health infrastructure and enhance its capacity to respond to emergencies such as a bioterrorist attack or outbreak of infectious disease. Consequently, many analysts will be evaluating the U.S. reaction to the SARS epidemic to identify any gaps in the public health system response and address them accordingly in order to be better prepared for a future event involving bioterrorism or emerging infectious disease.

In FY2002, the Department of Health and Human Services (HHS) provided a total of $1.075 billion for public health emergency preparedness to the 50 states, three municipalities (New York City, Chicago, and Los Angeles County) and the territories. Of the FY2002 total, CDC received $940 million for state and local public health preparedness which was distributed across the following six focus areas: preparedness planning and readiness assessment (~30% of grant funds); surveillance and epidemiology (20%); laboratory capacity — biological agents (15%); Health Alert Network/communications and information technology (15%); risk communication and health information dissemination (5%); and education training (10%). The Health Resources and Services Administration (HRSA) received $135 million of the FY2002 total for hospital preparedness and infrastructure. The

[14] The FDA guidance document can be found at [http://www.fda.gov/cber/gdlns/sarsbldgd.htm].

funding is for the development and implementation of regional plans to improve the capacity of hospitals, their emergency departments, outpatient centers, emergency medical services (EMS) systems, and other collaborating entities for responding to incidents requiring mass immunization, treatment, isolation and quarantine in the aftermath of bioterrorism or an outbreak of infectious disease.

In FY2003, CDC received $938.9 million and HRSA received $514.6 million, for a total of $1.45 billion to further enhance state and local preparedness. HRSA will also provide $28 million to academic health centers for a new initiative on preparedness to enhance curricula in health professions schools and provide continuing education/ training for practicing health care providers. Guidance documents for states and other eligible entities from CDC and HRSA on preparing applications for FY2003 funds were issued on May 2, 2003 and are available on the agencies' websites.[15]

On May 7, 2003, before the House Oversight and Investigations Subcommittee, the General Accounting Office (GAO) identified a number of gaps in public health preparedness that could interfere in the nation's response to a disease threat such as SARS.[16] In site visits to seven cities and their respective state governments, GAO found that the level of preparedness varied and planning for regional coordination was lacking. The state and local officials identified communication problems, inadequacies in their surveillance systems and laboratory facilities, and workforce shortages due to state budget cuts and a shortage of people with the necessary skills. Most hospitals lacked the capacity to treat a large influx of infectious disease patients due to already overcrowded emergency departments, lack of adequate medical equipment, personal protective supplies, isolation facilities, and staff. While four out of five hospitals surveyed by GAO reported having developed an emergency response plan for large-scale infectious disease outbreaks, few have participated in drills or exercises.

In testimony on May 21, 2003, before the Senate Permanent Subcommittee on Investigations, Dr. Michael Osterholm, director of the Center for Infectious Disease Research at the University of Minnesota stated that he believed that there will be a resurgence of SARS early next winter "that could far exceed our experience to date." Dr. Osterholm stated that given the transmission of the SARS virus in China and Taiwan, the respiratory disease "has now seeded itself in a significant number of humans as to make its elimination impossible. ...As a student of the natural history of infectious diseases, I am convinced that like the early days of the HIV epidemic, the worst of SARS is yet to come." When asked at the hearing for their opinion on the future impact of SARS, both Dr. Julie Gerberding, Director of CDC, and Dr. Anthony Fauci, Director of NIAID, agreed with the assessment made by Dr. Osterholm. Dr. Osterholm stated that the public health system remains underfunded in the U.S.; not only is more money required, but also additional qualified personnel "who will serve on the front lines of our ever increasing battles."

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[15] CDC at [www.bt.cdc.gov/planning/continuationguidance/pdf/guidance_intro.pdf] HRS at [ftp.hrsa.gov/hrsa/bioterror/bhppguidance.pdf].

[16] SARS Outbreak: Improvements to Public Health Capacity Are Needed for Responding to Bioterrorism and Emerging Infectious Disease, May 7, 2003, GAO-03-769T.

Also testifying at the May 21, 2003, Senate hearing was Dr. Mary Selecky, Secretary of the Washington State Department of Health and President of the Association of State and Territorial Health Officials. Dr. Selecky spoke of the strains currently experienced in her state by public health workers who are responding to emergencies, such as the smallpox vaccination program, SARS, West Nile virus, the outbreak of Bovine Spongiform Encephalopathy (BSE) in Canada, as well as working on routine communicable diseases and preventative health issues. Dr. Selecky described the challenges in coordinating between the various levels of government in how her office, CDC, and local health officials investigated whether the respiratory symptoms experienced by crew members of a container ship in the Tacoma, Washington port were consistent with the SARS case definition. "While CDC's Division of Global Migration and Quarantine was helpful, their resource limitations made it difficult to respond to all of the questions and calls for assistance pouring in from across the country." Dr. Selecky agreed with Dr. Osterholm that state and local health departments are facing a serious shortage of trained public health professionals. She stated that according to the National Association of State Personnel Executives, states are facing up to a 40% loss in employees due to retirement over the next 5 years, and the health workforce is the area in which the resulting shortages will be the most severe.

In conclusion, although most experts agree that recent increases in funding for public health has been critical, they believe that continued investment is necessary in order to redress the decades of neglect in the nation's public health infrastructure. Given the serious budget deficit problems experienced at the state and local levels, it is likely that state and local governments will look to the federal government for continued support in the effort to enhance public health preparedness.

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